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10/507,359	09/10/2004	Johan Bernard Ubbink	115808-504	5698
29157 7590 04/24/2008 BELL, BOYD & LLOYD LLP P.O. Box 1135 CHICAGO, IL 60690				
EXAMINER BADR, HAMID R				
ART UNIT 1794		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

Attachment to Advisory Action

The response, filed on 04/11/2008, to the final office action is acknowledged.

Applicant arguments are being fully considered.

In this communication Okonogi (hereinafter R1), Klapwijk (hereinafter R2) and Van Lengerich (hereinafter R3) are being cited. Attention is drawn to the following points:

1. R1 is directed to pelletized compositions (Col. 3, lines 9-12, and admitted by applicant response on page 4, line 11) and the water content of the core material is preferably as low as possible, less than 5% (w/w). (Col. 3, lines 22-23). In example 1, R1 discloses a granular product composed of granulated sucrose, propyleneglycol palmitic ester (binding material) and dried viable bifidobacteria. It is true that R1 does not directly disclose the water activity of this composition, however, such a composition does not indicate to have a water activity higher than 0.3.

The office action states that R1 is silent regarding the water activity of the composition, however, the office action does not admit that the water activity of R1's composition is higher than 0.3.

Summarizing R1: a pelletized composition, carrying active bifidobacteria with a moisture content of less than 5% (w/w) which can be further processed for enteric coating.

2. R2 clearly discloses the importance of controlling the water activity when dealing with lactic acid bacteria in a dry environment. R2 teaches that the water activity of supported lactic acid bacterial compositions may not exceed 0.3 and preferably below 0.15. Claim 1 of the instant application is limiting the water activity to below 0.3.

Applicants argue that R2 does not disclose compacted compositions. However, note that while R2 does not disclose all the features of the present claimed invention, R2 is used as teaching reference, and therefore, it is not necessary for this secondary reference to contain all the features of the presently claimed invention, *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973), *In re Keller* 624 F.2d 413, 208 USPQ 871, 881 (CCPA 1981). Rather this reference teaches a certain concept, and in combination with the primary reference, discloses the presently claimed invention.

Applicant's argument that "even if this composition has a water activity of 0.3 or less, it is still not a compacted composition....". Attention is drawn to the fact that R2 is teaching that to protect the lactobacilli, the water activity must be kept below 0.3. This means that whether in R1 the pellet is stored as is or if it is a part of another structure it must maintain the water activity below 0.3. Page 5, lines 5-8, example 1, demonstrates the effect of low water activity on storage of the product for several months. R2 does not teach the compaction process.

3. R3 discloses a probiotic delivery system for *Lactobacillus acidophilus*. The matrix used is ground cookies. R3 further discloses that the extruded pieces or pellets may be

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compressed in conventional tablet presses to obtain compressed versions of the extruded pellets.

R3 is also being used as teaching reference, and therefore, it is not necessary for this secondary reference to contain all the features of the presently claimed invention. The compression of pellets is being disclosed by this reference. However the delivery system disclosed by R3 is analogous to the presently claimed invention.

While R3 does not disclose any water activity levels for its probiotic delivery system, in the absence of data, cookies containing non-gelatinized starch are generally of low water activity. Further, R3 is not used to teach water activity. This is already taught by R2. Applicant asserts that the moisture level and non-gelatinized starch, in cookies, are generally characteristics of systems with higher water activity. Attention is drawn to the fact that in cookies, sugar, salts, proteins and starch all contribute to the final water activity of the product. Applicant is assuming that the cookie formulation includes a substantial amount of water and since the starch is non-gelatinized, therefore the water is not bound and is free. R3's statement as quoted by applicant "starch is not substantially gelatinized because sufficient amounts of water are not accessible to the starch at elevated temperatures". This is true specially when there is not much water to start with. As stated earlier, there are other contributing factors in determining the water activity in baked cookies. It is again emphasized that teachings of R2 regarding water activity of compositions containing live organisms are fundamental to designing such compositions.

The applicant's assertion that R3 teaches away from pelletized compositions is not persuasive. Attention is drawn to page 32 lines 11-13 where in embodiments of the invention; the pieces or pellets may be compressed in conventional tablet presses to obtain compressed versions of the extruded pellets.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-T 5:00 to 3:30 (Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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